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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,774	04/02/2004	Shotaro Yamaguchi	Q80844	1205

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

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06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/815,774	YAMAGUCHI, SHOTARO	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,27,31-33 and 36-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-27, 31-33, 36-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 26-27, 31-33, 36-47 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 3-26-07, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Examiner acknowledges the updating of the 1st line of the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-27, 31-33, 36-37, 39-45, 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide or a composition comprising SEQ ID NO:6 encoded by the polynucleotide with SEQID NO:5 wherein the polypeptide is an enzyme which is capable of deamidating amido groups in target proteins and peptides by directly acting upon said amido groups without cutting peptide bonds and without cross-linking said target proteins or peptides, and a method for producing said polypeptide by culturing a transformed cell, transformed with a vector comprising the polynucleotide encoding the amino acid sequence SEQ ID NO:6 does not reasonably provide enablement for any or all such polypeptides isolated from any or all microorganisms including those listed in the above claims and including variants, mutants and recombinants isolated from any or all sources or including variants, mutants and recombinants an amino acid sequence which is 80% identical to SEQ ID

NO:6.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 26-27, 31-33, 36-37, 39-45, 47 are so broad as to encompass any deamidating enzyme from any or all sources including some specific microorganisms such as those of the family *Flavobacteriaceae*, order *Cytophagales* etc. and variants, mutants and recombinants that are 80% identical to SEQ ID NO:6. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of enzymes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of only single specific deamidase having an amino acid sequence SEQ ID NO:6. It would require undue experimentation of the

skilled artisan to make and use the polypeptides as claimed. The specification is limited to teaching the SEQ ID NO: 6 as the specific enzyme but provides no guidance with regard to the making of variants and mutants of SEQ ID NO:6 or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the polypeptides for use in the claimed method, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to make and use the full scope of the polypeptides encompassed by this claim. While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompasses any or all deamidating enzymes including polypeptides comprising modifications in up to 20% of the amino acids of SEQ ID NO:6 and fragments of the same because the specification does not establish: (A) regions of the protein structure which may be modified without affecting deamidating activity; (B) the general tolerance of said deamidases to modification and extent of

such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue on the polypeptide SEQ ID NO:6 with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful; (E) a rational and predictable scheme to isolated said enzyme from the different microbial sources listed in the claims which includes variants and mutants of said enzyme.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including polypeptides with an enormous number of amino acid modifications in SEQ ID NO: 6. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics for use in the claimed method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicants have filed a Declaration under Rule 1.132 as well as arguments traversing the above rejection. Applicants, in their argument argue that claims have been amended to cover enzymes obtained from specific microorganisms and these claim amendments address all the rejections under 35 U.S.C. 112, 1st paragraph. In the Declaration, Mr. Yamaguchi argues that the Examiner is incorrect in asserting that one of ordinary skill in the art must be prodded with guidance for the selection of which of the infinite number of variants have the claimed property. This is because the selection occurs by ruling out

all sequences that do not have sufficient homology and/or that do not hybridize with the polynucleotide which has the nucleotide sequence of SEQ ID NO:5 and that this selection step narrows the remaining candidates to nucleotide sequences that are generally expected to encode an active enzyme. Mr. Yamaguchi also argues that as evidence that his opinion is sound, the nucleotide sequence of the deamidation enzyme of the present application (U.S. Application No: 10/815,774, related to *Chryseobacterium gleum* and that of related application No: 09/727,769, re *Chryseobacterium sp.* NO. 9670 are about 76 % homologous and that this is compelling evidence that percent homology is a sufficient basis on which to expect that nucleotide sequences having 80% homology with a nucleotide sequence encoding an active enzyme will also encode an active enzyme.

Examiner respectfully disagrees. First of all, applicants are not simply claiming enzymes that have 80% sequence homology with that of SEQ ID NO:6. Instant claims, when considered broadly, are drawn to any mutants and variants of SEQ ID NO:6 from any source including all those microorganisms that have been listed in the claims. As argued by the Examiner in the rejection, the specification fails to provide any specific guidance for making the specific amino acid modifications either in SEQ ID NO:6 or any other polypeptide such that one of ordinary skill in the art can successfully obtain a variant. Contrary to Mr. Yamaguchi's argument without specific guidance one of ordinary skill in the art will be subject to undue experimentation of making and testing an extremely large number of polypeptide sequences. Therefore, instant claims are not enabling.

Claims 26-27, 31(a)-(b) -33, 36-37, 39-45, 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 26-27, 31(a)-(b) -33, 36-37, 39-45, 47 are directed to any or all polypeptides having deamidase activity and isolated from various sources and polypeptides and fragments corresponding to variants, mutants and recombinants of SEQ ID NO:6 as well as method of making said polypeptide using transformed cells. Claims 26-27, 31(a)-(b) -33, 36-37, 39-45, 47 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides including those derived from SEQ ID NO:6, including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in SEQ ID NO:6 and fragments of SEQ ID NO:6 and those isolated from various sources, that have not been disclosed in the specification as well as method of making said polypeptides using transformed cells. No description has been provided of all the sequences encompassed or the modified polypeptide sequences encompassed by the claim. No information, beyond the characterization of SEQ ID NO:6 has been provided by applicants, which would indicate that they had possession of the genus of polypeptides or a method of making the same. The specification does not contain any disclosure of the structure of all the polypeptide sequences derived from SEQ ID NO:6, including fragments and variants within the scope of the genus of polypeptides to be used in the claimed method. The genus of polypeptides required for the claimed method is a large variable genus including peptides, which can have a wide variety of structures. Therefore many structurally unrelated polypeptides are encompassed within the scope of these claims. The

specification discloses only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features o fall species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

In response to the previous Office action, applicants traverse the above rejection arguing that claims have been amended to cover enzymes obtained from specific microorganisms and these claim amendments address all the rejections under 35 U.S.C. 112, 1st paragraph. Examiner respectfully disagrees. These claims as amended continue to suffer from written description deficiencies as explained in the above rejection. As discussed in the written description guidelines, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. **Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.** Satisfactory disclosure of a representative number depends on whether one of skill in the art

would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. In the instant case the claimed polypeptides comprise a genus and includes species which are widely variant in structure. The genus encompassed in the above claims is structurally diverse as it encompasses polypeptides with deamidase activity but isolated from various different sources or modified amino acid sequences. As such, neither the description of the structure and function of SEQ ID NOS:6 nor the disclosure solely of functional features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus. Therefore the above rejection is maintained.

Claims 38 and 46 are rejected because the invention appears to employ a novel *Chryseobacterium* microorganism. Since the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed microorganism is not fully disclosed, nor has been shown to be publicly known and freely available. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. Accordingly, it is deemed that a deposit of the microorganism should have been made in accordance with 37 CFR 1.801-1.809. In order for the claims to be enabled, applicants must show that either the microorganism can be made by publicly available materials or that the microorganism as such has been deposited in such a way that it is freely available to the public.

The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. It is clear that applicant has made a deposit under the Budapest Treaty, however, its public availability is not clear.

Since the biological deposit has made under the terms of the Budapest Treaty, an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific plasmid/strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

In response to the previous Office action, applicants argue that the deposit has been made under the Budapest treaty as evidenced by the attached receipt of deposit document from the PCT branch, which was filed in the parent application, now USP 6,756,221 and that this certificate should obviate the rejection. While Examiner acknowledges that applicants have filed the Biological Deposit certificate for having deposited the strain in a Japanese Depository, they have failed to provide an affidavit or a Declaration stating that the specific plasmid/strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent. Until such time Examiner will continue to maintain the above rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vaintraub et al. and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2nd Ed, Cold Spring Harbor Laboratory Press, 1989, pages 7.37-7.52). Claim 31 is drawn to a recombinant deamidase obtained by culturing a transformed cell, transformed with a vector comprising a polynucleotide encoding a deamidase which is capable of deamidating amido groups in target proteins and peptides by directly acting upon said amido groups without cutting peptide bonds and without J cross-linking said target proteins or peptides, wherein said polypeptide either has the amino acid sequence SEQ ID NO:6 or is a mutant, or variant of SEQ ID NO:6. The reference of Vaintraub et al., teaches a deamidase which the Examiner argues as inherently being the same as that claimed in this application. However, while the reference teaches the method of isolating, purifying and characterizing the enzyme the reference does not teach a recombinant enzyme. Sambrook et al. teach exhaustive methods of making recombinant protein starting from a purified protein, which has been used by a number of inventors to arrive at recombinant protein starting from a purified protein. Therefore combining the teachings of the above two references, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Vaintraub et al. et al. with that of Sambrook et al. to arrive at a recombinant protein. One of ordinary skill in the art would be motivated to do this in order to prepare large amounts of the protein. One would have a reasonable expectation of success since Vaintraub et al. provide the

purified protein and Sambrook et al. teach a reliable and time-tested method that has been used by a number of other inventors.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(0 or (g) prior art under 35 U.S.C. 103(a).

In response to the previous rejection, applicants extend their argument from the argument traversing the rejection sunder 102(b) that the enzyme preparation of Vaintraub et al. is definitely different from the enzyme of the present application. Arguing the previously held rejection of claims under 35 U.S.C. 102(b) using the reference of Vaintraub et al., applicants submit that the enzyme preparation of Vaintraub et al. is obtained from plant seeds at the germination stage and thus cannot anticipate the microorganism product of the claimed invention. Applicants argue, because the enzyme preparation of Vaintraub et al. is a partially purified product there is a **possibility** that the deamidation activity observed by Vaintraub et al. is based on the contaminated protease alone or the contaminated protease with peptidoglutaminase and/or glutaminase. Applicants maintain that plant seeds generally contain reserve proteins that have a high amount of amido groups, such as gluten and accordingly, one skilled in the art might

consider the existence of a protein-deamidating enzyme in plant seeds based on the assumption that such enzyme would be required to assimilate the nitrogen derived from the amido groups, but however, this is not the same for the microorganisms. Examiner respectfully disagrees. All the above arguments are rendered moot because the enzyme of claim 31 is not specifically drawn to an enzyme from a microorganism but drawn to any or all variants, which when considerd broadly includes enzymes from any or all sources. Furthermore, this is an obviousness rejection and therefore, applicants' assumption that there is a possibility that the reference enzyme to be contaminated or that the enzyme is a crude preparation does not hold water because, one of ordinary skill in the art would be knowledgeable to expect and understand all the above situations described by the applicant and take appropriate measures to avoid all such pit falls and arrive at a purified enzyme as claimed herein. In short applicant's arguments are mostly based on assumptions and possibilities rather than scientific facts. Therefore, Examiner continues to maintain the above rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 26-27, 32-33, 36-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,251,651. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 26-27, 32-33, 36-47 of the instant application and claims 1-3 of the reference patent are both directed to enzyme having the deamidase activity and its variants. Among all the different variants claimed in the instant application and in the reference patent a good number of variants are identical to one another. The portion of the specification (and the claims) in the reference patent that supports the recited variants includes several embodiments that would anticipate the variants claimed in claims 26-27, 32-33, 36-47 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims 1-3 of the reference patent when there is specifically recited embodiment that would anticipate mainly claims 26-27, 32-33, 36-47 of the instant application. Alternatively, claims 26-27, 32-33, 36-47 cannot be considered patentably distinct over claims 1-3 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1-3 of that patent and falls within the scope of claims 26-27, 32-33, 36-47 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1-3 of the reference by selecting a specifically disclosed embodiment that supports those claims. One of ordinary

skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-3 of the reference patent.

Claim 31 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 6,251,651. This is a double patenting rejection.
In response to the previous Double patenting rejection, applicants argue claims 28 and 30 are canceled making the rejection against them now moot. Applicants also argue that U.S. patent No. 6,251,651 claims an isolated polypeptide (claims 1 and 2) and a recombinant polypeptide (claim 3) as opposed to the invention set forth in claim 39 of the present application wherein the enzyme claimed in claim 39 is not an enzyme itself but a composition comprising an isolated enzyme, namely, the invention of claim 39 is not the same as those claimed in the prior USP 6,251,651. Examiner respectfully disagrees and is at a loss to understand the applicant's argument. Irrespective of how the invention is claimed, the current claim 31 and the claims of the issued patent are identical. Therefore, Examiner continues to maintain the above rejection.

Conclusion

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

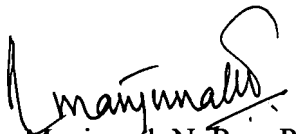
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

June 5, 2007